REMARKS

Status of the Claims

Claims 1, 5, 7-18, 22-25, 27, 31-33, 35, 37, and 43-54 were pending. Claims 37, 44 and 45 have been amended. No new matter has been added. Claims 37, 43-45 and 49-54 are currently under examination.

Claim Amendments

Claim 37 has been amended to recite " papillomavirus capsid L1" instead of "papillomavirus L1." Support for this amendment can be found throughout the application but at least at page 6 lines 7-17 of the application as filed.

Claims 44 and 45 have been amended to correct claim dependency from claim 42, now canceled, to claim 37.

Claim Objections

On page 2, the Action recites that "Claims 44-45 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 42 has been canceled…" The Applicants submit that claims 44 and 45 have been amended to correct claim dependency to claim 37 instead of claim 42. The Applicants request removal of the rejection.

35 USC §102

On page 3, the Action asserts that "Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Gissman et. al (U.S. Patent no. 7,371,391 B2) [hereinafter, "Gissmann"]…The above cited patent clearly anticipates the broad limitations of the claimed invention. Gissmann et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere (see abstract, and claims 1-14)." The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that Gissmann recites "Vaccine formulations comprising viral capsomeres…Therapeutic and prophylactic methods of use for the vaccine formulations…" (see Abstract). Gissmann fails to disclose "a second polypeptide comprising at least one immunogenic epitope" elements of independent claim 37. The Applicants submit that Gissmann recites papilloma virus L1 protein and "adjacent amino acid residues from a second

protein," (see independent claim 1). Therefore, Gissmann fails to disclose elements of at least independent claim 37. The Applicants request removal of the rejection.

On page 3, the Action asserts that "Claims 37, 43, 50 and 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et. al (U.S. Patent no. 6,908,613 B2) [hereinafter, "Wilson"] ...The above cited patent clearly anticipates the broad limitations of the claimed invention. Wilson et al taught chimeric protein comprising papillomavirus L1 protein and another protein (see abstract, and claims 1, 3-5)." The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that Wilson recites "Disclosed are chimeric HPV LI proteins and virus like particles...The disclosed chimeric HPV L1 proteins and VLPs are useful..." (see Abstract). Wilson fails to disclose "a second polypeptide comprising at least one immunogenic epitope" elements of independent claim 37. The Applicants submit that Wilson recites "A chimeric HPV L1 protein comprising HPV-18 L1 protein and HPV-45 L1 protein" (see independent claim 1) and "A method of treating papillomavirus caused by at least one of HPV-18 and HPV-45 comprising administering to a patient an effective amount of the protein of claim 1" (see claim 5 of Wilson). Therefore, Wilson fails to disclose elements of at least independent claim 37. The Applicants respectfully request removal of the rejection.

On page 3, the Action asserts that "Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallek et. al (U.S. Patent no. 7,182,947 B2) [hereinafter, "Hallek"] ...The above cited patent clearly anticipates the broad limitations of the claimed invention. Hallek et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere (see abstract, and claims 1-15)." The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that Hallek recites "Vaccine formulations comprising viral capsomeres are disclosed along with methods for their production..." (see Abstract). Hallek recites "A protein encoded by an...encoding a truncated HPV L1 protein... wherein said protein is immunogenic against HPV," (see independent claim 1 of Hallek). Hallek recites in claim 2 "A protein encoded by...encoding a fusion protein, said fusion protein comprising an amino acid sequence of a truncated first HPV L1 and an amino acid sequence of a second HPV proteins...said second HPV protein is selected from the group consisting of E1, E2..." Hallek recites in claim 5, "A protein of claim 2 wherein said HPV protein is an HPV E7 protein." The Applicants respectfully submit that Hallek recites "the second protein be selected from the group

E1, E2, E3, E4, E%, E6, and E7-early gene products encoded in the genome of papilloma virus strains HVP6…" (see Hallek column 4 lines 22-27).

The Applicants respectfully point out that Halleck fails to disclose "a second polypeptide comprising at least one immunogenic epitope" elements of independent claim 37. In addition, Hallek fails to disclose "wherein the capsomere has a ratio of 1 chimeric protein to 5 papillomavirus L1 polypeptides," elements of dependent claim 50. Hallek fails to disclose "wherein the second polypeptide is derived from a viral-associated protein or a tumor antigen" elements of dependent claim 54. Therefore, Hallek fails to disclose elements of at least independent claim 37 and dependent claims 50 and 54. The Applicants respectfully request removal of the rejection.

On pages 3-4, the Action asserts that "Claims 37, 43, 50 and 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Mizzen et. al (U.S. Patent no. 6,524,825 B1) [hereinafter, "Mizzen"] …The above cited patent clearly anticipates the broad limitations of the claimed invention. Mizzen et al taught fusion protein comprising papillomavirus L1 protein and another protein (see abstract, and claims 1-15)." The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that Mizzen recites "compositions comprise an HPV protein joined to a stress protein (or heat shock protein (HSP))…" (see Abstract). Mizzen recites "A fusion protein comprising a human papillomavirus (HPV) antigen, or an antigenic portion thereof, and a stress protein thereof…," (see independent claim 1 of Mizzen).

The Applicants respectfully point out that Mizzen fails to disclose "a second polypeptide comprising at least one immunogenic epitope" elements of independent claim 37. In addition, Mizzen fails to disclose "wherein the capsomere has a ratio of 1 chimeric protein to 5 papillomavirus L1 polypeptides," elements of dependent claim 50. Mizzen fails to disclose "wherein the second polypeptide is derived from a viral-associated protein or a tumor antigen" elements of dependent claim 54. Therefore, Mizzen fails to disclose elements of at least independent claim 37 and dependent claim 50. The Applicants request removal of the rejection.

35 USC §102

On page 4, the Action asserts that "Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Gissman et. al (U.S. Patent no. 6,228,368 B1) [hereinafter, "Gissmann2"]…The above cited patent clearly anticipates the broad limitations of the claimed invention. Gissmann et al taught chimeric protein comprising papillomavirus L1 protein and

another protein wherein the composition forms capsomere (see abstract, and claims 1-14)." The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that Gissmann2 recites "Vaccine formulations comprising viral capsomeres…Therapeutic and prophylactic methods of use for the vaccine formulations…" (see Abstract). The Applicants submit that Gissmann2 recites …papilloma virus L1 protein and "adjacent amino acid residues from a second protein…said second protein positioned to inhibit virus-like particle formation…," (see independent claim 1). Gissmann2 recites " "wherein the amino acid residues of the second protein are derived from an HPV protein" (see dependent claim 12). Gissmann2 fails to disclose "a second polypeptide comprising at least one immunogenic epitope" elements of independent claim 37. In addition, Gissmann2 fails to disclose "wherein the capsomere has a ratio of 1 chimeric protein to 5 papillomavirus L1 polypeptides," elements of dependent claim 50. Gissmann2 fails to disclose "wherein the second polypeptide is derived from a viral-associated protein or a tumor antigen" elements of dependent claim 54. Therefore, Gissmann2 fails to disclose elements of at least independent claim 37 and dependent claims 50 and 54. The Applicants request removal of the rejection.

On pages 4-5, the Action asserts that "Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Garcea et. al (U.S. Patent no. 6,,165,471 A) [hereinafter, "Garcea"]…The above cited patent clearly anticipates the broad limitations of the claimed invention. Garcea et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere (see abstract, all the claims, specifically claims 1-19). Additionally, under inherency doctrine where the claims and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See In re Best, 562 F. 2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)." The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that Garcea recites "stable HPV capsomeres which express at least one virus-neutralizing conformational epitope of a native HPV L1 protein which are substantially capsomeres…"(see Abstract). Garcea fails to disclose "A chimeric protein comprising…a first polypeptide comprising a papillomavirus capsid L1; and…a second polypeptide comprising at least one immunogenic epitope" elements of independent claim 37. In addition, Garcea fails to disclose "wherein the capsomere has a ratio of 1 chimeric protein to 5

papillomavirus L1 polypeptides," elements of dependent claim 50. Garcea fails to disclose "wherein the second polypeptide is derived from a viral-associated protein or a tumor antigen" elements of dependent claim 54. Therefore, Garcea fails to disclose elements of at least independent claim 37 and dependent claims 50 and 54. The Applicants request removal of the rejection.

The Applicants respectfully submit that independent claim 37 is in condition for allowance. Because claims 43-45 and 49-54 depend from and contain all the elements of independent claim 37 plus additional elements, claims 43-45 and 49-54 are also in condition for allowance.

CONCLUSION

For at least the reasons stated above, the Applicants respectfully submit that claims 37, 43-45 and 49-54 are in condition for allowance. Please feel free to call the undersigned, if additional response is required.

Respectfully submitted,

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